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EXAMINER	
KATAKAM, SUDHAKAR	
ART UNIT	PAPER NUMBER
1621	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/07/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,419	GALVEZ ET AL.	
	Examiner	Art Unit	
	Sudhakar Katakam	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically preventing or treating cancer, does not reasonably provide enablement for "preventing or treating cancer" as claimed.

The claims sets forth the preventing or treating cancer in a mammal comprising administering to a mammal a therapeutically effective amount of the composition of linolenic acids. However, there never has been a composition capable of treating cancer generally. There are compositions or compounds that treat a range of cancers, but no one has ever been able to figure out how to get a composition to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective anti-tumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses, exposure to chemicals, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent

to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such task.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation", it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. 2164.

In the instant case, the claims cover "preventing or treating cancer in a mammal comprising administering to a mammal a therapeutically effective amount of the composition of linolenic acids". Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not, because "preventing or treating cancer" with the composition of linolenic acids composition is speculative.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. 2164.05 (a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of

ordinary skill would go about practicing the invention from the claim to "preventing or treating cancer" in a mammal with the composition of linolenic acids.

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, claims 15-17 are prima facie non-enabled for their full scope.

With regard to rejection under 35 USC 112 first paragraph, the following factors have been carefully considered (In re Wands, 8 USPQ2d 1400; CAFC, 1988):

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

(1). **Nature of the invention**: As indicated above, the "preventing or treating cancer" in a mammal with the composition of linolenic acids.

(2). **Breadth of the claims**: Some of the claims are extremely broad. In particular claim 15 and 16 that read on specifically "preventing or treating cancer" in a mammal with the composition of linolenic acids.

(3). **State of the Prior Art**: There is no known treating or preventing of cancer with the claimed composition. The prior art teaches compositions of linolenic acids use as anti-tumor agents [**Shirai et al** (JP 2000336029 A)]. Hence, the compositions of linolenic acids are known useful agents in a variety of compositions.

(4). **Unpredictability of the Art**: The instant case is drawn to the "preventing or treating cancer" in a subject matter. "Preventing or treating cancer" is a subject with the

compositions of linolenic acids of present invention is speculative. Applicants' claim to "preventing or treating cancer" is a subject with the composition of linolenic acids is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(5). **Amount of Guidance Provided**: Applicants have provided no guidance for using the claimed method to "preventing or treating cancer" in a subject. For instance, applicants state that an effective amount of the composition of claims 15-17 should be administered to the said subject. However, when considering that the claims read on the "preventing or treating cancer" to the subject in need of the medication, it becomes critical to know how long does one administers the said compound for the "preventing or treating cancer". This is critical to the practice of the invention and therefore should adequately be disclosed.

(6). **Presence or Absence of Working Examples**: There are no examples of "preventing or treating cancer" in a subject disclosed. Applicants only disclose few examples showing the treatment of tumor cell growth in a subject in need of the compositions of linolenic acids.

(7). **Ordinary Skill in the Art**: The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. This is a new field with no known success for the "preventing or treating cancer" with composition of linolenic acids.

(8). **Amount of Experimentation Necessary**: A great deal of experimentation is required. In lie of the fact that no animal models exist which can reasonably suggest

successful "preventing or treating cancer" with the composition of linolenic acids, it will be necessary for an ordinary skilled artisan to have clinical data in order to practice the claimed invention.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for the "preventing or treating cancer" with the composition of linolenic acids.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 provides for the use of the composition for dying oil in varnishes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Sih et al** (US 6,316,645).

The instant claims are drawn to a composition comprising a mixture of linolenic acids, viz., 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid, characterized in that said linolenic acids are present in a ratio of 1:1 w:w and said mixture varying between 30% and 90% by weight relative to the weight of the composition.

Sih et al disclose a composition of linolenic acids, which comprises 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid, and other linolenic acids [see Fig.2]. It also discloses that the crude reaction product comprises these compounds [see examples].

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S. Application No.10/523,863.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

They generically overlap. The applications are drawn to a process for the preparation of a composition comprises conjugated linolenic acids, viz., 9cis,11trans,15cis-octadecatrienoic acid, and 9cis,13trans,15cis-octadecatrienoic acid. The mixture can be purified by liquid chromatography.

The difference between the instant claims and the claims in the copending application is that the instant claims characterized the ratios of the components in the mixture, whereas copending application is silent on these ratios (as can be seen from examples).

It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teachings of the cited copending applications to make instant applicants' process and to expect to the components in certain ratios in the composition. The difference, however, does not constitute a patentable distinct, because the claims in the present invention simply fall with in the scope of copending application, since the similar reactants and conditions. Hence the instant claims overlap with the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not been patented yet.

9. Claims 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S. Application Nos.10/523,863 in view of **Shirai et al** (JP 2000336029 A).

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

The instant claims are drawn to a method for preventing or treating cancer in a mamma comprising administering to a mammal a therapeutically effective amount of the composition comprising linolenic acids, viz., 9cis,11trans,15cis-octadecatrienoic acid, and 9cis,13trans,15cis-octadecatrienoic acid.

The claims of copending application are drawn to the conjugated linolenic acids and their nutraceutical applications. The conjugated linolenic acids are selected from the group consisting of 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid along with other linolenic acids.

The difference between the instant claims and the claims in the copending application is that the copending application uses 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid along with other linolenic acids as a nutraceutical application. However, the instant claims composition uses for preventing or treating the cancer, which comprises 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid, and silent on other linolenic acids in the composition.

With regard to the treating or preventing cancer, **Shirai et al** teach a breast cancer inhibiting agent contains a conjugated linolenic acids, which comprises of 9,11,13- octadecatrienoic acid, 10,12,14-octadecatrienoic acid, their mixture etc. [see abstract].

It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teachings of the cited copending applications to make instant applicants' process using **Shirai et al** teachings and to expect to the components in certain ratios in the composition. The difference, however, does not constitute a patentable distinct, because the claims in the present invention simply fall with in the scope of copending application, since the similar reactants and conditions. Hence the instant claims overlap with the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not been patented yet.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SK

J. PARSA
PRIMARY EXAMINER

2/5/2007